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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,132	05/25/2001	Jennifer L. Harris	18062G-003210	5089

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EXAMINER

LEARY, LOUISE N

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/866,132

Applicant(s)

HARRIS ET AL.

Examiner

Louise N. Leary

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-83 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 73-76 and 78-83 is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) 17,20,33,34,37-39,42 and 55-59 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6. 6) ☐ Other:

1. Claims 1-83 are pending in this application.
2. Claims 60, 72 and 77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 60 is indefinite because the meaning of the word "located" is ambiguous. The claim does not recite whether "located" means a physical location or is used to describe a peptide region. It is suggested that the meaning of the word be included in the claim limitations to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 72 is indefinite because the claim further describes a different "step c" for claim 61. Correction is required to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 77 is indefinite for depending from "claim 78". Correction is required to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16, 18-19, 21-32, 35-36, 40-41, 43-54, and 60-72 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Del Nery et al (Biochem. J., V.323, p 427-433 (1997)).

Del Nery et al describe a method that uses a peptidyl-MCA (methylcoumarin amide) combinatorial library and fluorogenic peptides to characterize the substrate specificity of the major cysteine protease (cruzipain) from *Trypanosoma cruzi*. The peptidyl-MCA substrates described encompasses the instant claim limitations when peptides R-P where R²⁰ is absent and Y is methyl and in which c=o. See the Abstract, Table 3 and the entire document. With respect to the database limitations set forth in the instant claims, Del Nery et al describe using amino acid analyzers in the methods. See page 428, "Experimental" section. It was well known in this art that the amino acid analyzers function electronically to create a peptide data base of the samples evaluated.

Thus, Del Nery et al disclose a material comprising at least one of the fluorogenic moieties described in the instant claims; a method for assaying the presence of an enzymatically active protease in a sample; a method for assaying for the presence of a selected microorganism in a sample; a fluorogenic peptide and library comprising peptide sequences as claimed except for stating the library comprises at least 100 to 1,000,000 peptides.

However, regarding the instant claim limitations describing the library comprising at least 100 to 1,000,000 peptides, it is noted that Del Nery et al describes a peptide library comprising 42 peptides and does not state the method can not be used for a library comprising greater than 42 peptides. Hence, Del Nery et al disclose the invention claimed except for describing a peptide library that inherently comprises at least 100 to 1,000,000 peptides, but does not limit the use of the materials and methods disclosed for evaluating a larger peptide library which anticipates or renders obvious the invention claimed.

The burden of proof is on applicants to show patentably distinct differences between the materials and methods described in the Del Nery et al disclosure and the present invention.

4. Claims 17, 20, 33-34, 37-39, 42, and 55-59 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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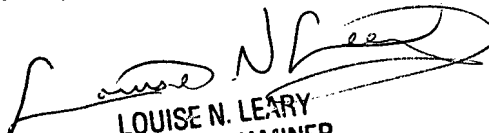
5. Claims 73-76 and 78-83 are allowable over the prior art of record.
6. The Sawada et al reference (Molecular Reprod. & Dev.; V.45, p240-243, (1996); the Morgan et al (US 5,872,207); the Brynes et al (US 4,897,444); the Powers et al (US 5,089,634); GB 23224529 A document; and the Morita et al reference (J. Biochem., V.82, p 1495-1498 (1977) have been cited to further show the state of this art.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is (703) 308-3533. The examiner can normally be reached on Monday to Friday from 9:30 to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703)308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1235.

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LOUISE N. LEARY
PRIMARY EXAMINER

February 8, 2003

Continuation of Disposition of Claims: Claims rejected are 1-16, 18-19, 21-32, 35-36, 40-41, 43-54, 60-72.